K010821

APR 1 1 2001

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

The following 510(k) Summary of Safety and Effectiveness is prepared and provided in accordance with the requirements of 21 CFR 807.92 as amended under the Safe Medical Devices Act of 1990 (SMDA).

Submitter's Information

Company Name:	Medi-Physics, Inc., DBA Nycomed Amersham Imaging
Address:	101 Carnegie Center Princeton, NJ 08540-6231
Contact Name:	Subhash Patel Senior Manager of Regulatory Affairs
Phone Number:	(609) 514-6846
Summary Prepared Date:	March 15, 2001

Subject Device Information

Trade Name:	EchoSeed™	Model: 6733
Common Name:	Radionuclide Brachytherapy Source	
Class:	II	
Classification:	21 CFR 892.5730	Product Code: 90-KXK

Predicate Device A legally marketed device to which equivalence is claimed.

Trade Name:	OncoSeed™	Model: 6711
Common Name:	Radionuclide Brachytherapy Source	
Class:	II	
Classification:	21 CFR 892.5730	Product Code: 90-KXK
Cleared 510(k) No.:	K914281	
Submitted by:	Medi-Physics, Inc., (DBA Nycomed Amersham Imaging)	

Description of Device

EchoSeed™ consists of a welded titanium capsule containing Iodine-125 adsorbed onto a silver wire. The specifically designed grooves on the outer surface of the capsule result in enhanced visualization of the seed under ultrasound. The seed is 4.55 ±0.35 mm in length and 0.8 + 0.16/-0.03 mm in outside diameter with 6 grooves on the outer surface of the capsule.

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The EchoSeed™ seeds are available with a range of apparent activities from 0.297 to 0.673 mCi (Air-Kerma Strength 0.377 to 0.855 μGym^2/hr) with a half-life of 59.43 days. The seeds are packaged in a screw cap glass vial container. The glass vial is packaged in a sealed lead container. They are considered approved as sealed sources by IDNS/NRC for distribution to licensed personnel only.

The principle radionuclide of the EchoSeed™ is Iodine-125 that decays by electron capture with emission of characteristic photons and electrons. Therefore, the useful shelf life of the sources should be determined by considering a) radioactive decay and b) leak test date. The package insert provides such information.

Intended Use

The subject 6733 EchoSeed™ brachytherapy source consists of Iodine-125 radionuclide, which is enclosed in a sealed titanium container and intended for medical purposes to be placed onto a body surface or into a body cavity or tissue as a source of nuclear radiation for therapy.

Indications for Use

EchoSeed™ seeds with standard apparent activities from 0.297 to 0.673 mCi (Air-Kerma Strength 0.377 to 0.855 μGym^2/hr) are indicated for permanent interstitial implantation of selected localized tumors which are of low to moderate radiosensitivity. They may be used as primary treatment of prostate cancer.

EchoSeed™ seeds are indicated to treat residual tumors concurrent with or at the completion of other treatment modalities, such as external beam radiation therapy or chemotherapy. In addition, recurrent tumors may be implanted with ^{125}I seeds.

When compared with the Intended Use and Indications for Use of the predicate model 6711 OncoSeed™, the Intended Use and Indications for Use of the model 6733 EchoSeed™ have not changed.

Technological Characteristics

The following modifications have been incorporated in the model 6733 EchoSeed™ device:

Modified Characteristics	**6733 EchoSeed** (Subject Device)	**6711 OncoSeed** (Predicate Device) Cleared in 510(k)# **K914281**
Number of uses	For Single Use	Single or Multiple use when product meets specified criteria
Application of product	Permanent Implant	Permanent or Temporary implants
Apparent Activity Range Air-Kerma Strength	0.297 to 0.673 mCi (0.377 to 0.855 μGym^2/hr)	0.1 to 1.0 mCi (0.127 to 1.27 μGym^2/hr)
Outer Capsule Material	A-40 Titanium Grooved Tube	A-40 Titanium Tube
Outer Surface of Capsule	6 grooves.	Smooth surface
Groove Specifications	Width: 0.50 ± 0.07 mm Depth: 0.045 ± 0.03 mm Shape: flattened sinus	Smooth surface
Visibility under ultrasound	Enhanced visibility	No change from K914281

All other technological characteristics of the subject EchoSeed™ remain unchanged compared to the predicate OncoSeed™ that was cleared in the 510(k) # K914281.

Nonclinical Test Data

The copies of the following Nonclinical Test Data reports have been provided in the **Section-G** of this submission.

1. An Evaluation of the Impact of Changes to the Titanium "Can" and the Addition of the Annealing Processes on Human Safety. Prepared and furnished by the Regulatory And Technical Associates, Lebanon, NJ.

2. Summary of 6733 Seed Research & Design Programme Report – by Audun Tornes, Morten Eriksen, and Dewi Lewis.

3. Ultrasound Reflective Properties of Competitor Seeds – by Audun Tornes

Conclusion:

Upon reviewing the safety and effectiveness information provided in this submission and comparing the intended use, indications for use, method of use and other technological characteristics, it can be concluded that the subject EchoSeed™ is substantially equivalent to the predicate OncoSeed™, which was cleared under 510(k)# K914281.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 1 2001

Subhash Patel
Senior Manager, Regulatory Affairs
Nycomed Amersham Imaging
101 Carnegie Center
PRINCETON NJ 08540-6231

Re: K010821
EchoSeed/Iodine-125 Seeds
Dated: March 16, 2001
Received: March 19, 2001
Regulatory Class: II
21 CFR §892.5730/Procode: 90 KXK

Dear Mr. Patel:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

EXHIBIT-2

Indications for Use Form

510(k) Number (if known): K010821

Device Name: 6733 EchoSeed™/Iodine-125 Seeds

Indications For Use:

EchoSeed™ seeds with standard apparent activities from 0.297 to 0.673 mCi (Air-Kerma Strength 0.377 to 0.855 $\mu Gym^2/hr$) are indicated for permanent interstitial implantation of selected localized tumors which are of low to moderate radiosensitivity. They may be used as primary treatment of prostate cancer.

EchoSeed™ seeds are indicated to treat residual tumors concurrent with or at the completion of other treatment modalities, such as external beam radiation therapy or chemotherapy. In addition, recurrent tumors may be implanted with ^{125}I seeds.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyman

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K010821

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)